

DETAILED ACTION

The response filed March 18, 2008 presents remarks and arguments submitted to the office action mailed April 10, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 112 first paragraph rejection of Claims 10, 12-16 and 17 is persuasive due to the amendments made to the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of 1, 2, 4-7, and 9 over DeLuca et al. (6392071) in view of Wu (5981597) is not persuasive. Therefore, the rejection is herewith maintained for the reasons of record.

Applicant's arguments over the Obvious Double Patenting rejection of Application No. 10/235244, Application No. 11/283291, Application No. 11/283090, and U.S. Patent No. 6,989,377 is not persuasive. Therefore, the rejection is herewith maintained for the reasons of record.

The rejections of record are restated below for Applicants convenience:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (6392071) in view of Wu (5981597).

DeLuca et al teaches a novel class of vitamin D related compounds, namely, the 2-alkylidene-19-nor-vitamin D derivatives, as well as a general method for their chemical synthesis (abstract). Subsequently, in Example 2, DeLuca et al teaches the "Preparation of 20(S)-1.alpha.,25-dihydroxy-2-methylene-19-nor-vitamin D3 (col. 15 line 45)." The reference further teaches the "compounds are characterized by relatively high intestinal calcium transport activity and relatively high bone calcium mobilization activity resulting in novel therapeutic agents for the treatment of diseases where bone formation is desired, particularly low bone turnover osteoporosis. These compounds also exhibit pronounced activity in arresting the proliferation of undifferentiated cells and inducing their differentiation to the monocyte thus evidencing use as anti-cancer agents and for the treatment of diseases such as psoriasis (see abstract)." "The treatment may be transdermal, oral or parenteral. The compounds may be present in a composition in an amount from about 0.1 ug/gm to about 50ug/gm of the composition, and may be administered in dosages of from about 0.1 ug/day to about 50 ug/day (col 5, lines 30-40)," falling within the amount limitations as recited in claim 7.

DeLuca et al. fails to specifically teach the compound 20(S)-1.alpha.,25-dihydroxy-2-methylene-19-nor-vitamin D3 in the treatment of ulcerative colitis.

Wu teaches "...during intestinal inflammatory states, however, there is an alteration in this pattern of epithelial differentiation. There is an increase in epithelial proliferation with an expansion of cell populations in an undifferentiated state, referred to as crypt hypertrophy." "A hyperproliferative state also occurs in the colonic

epithelium during inflammatory states such as ulcerative colitis and parasitic infections (col 3, lines 15-30).”

It would be obvious to one of ordinary skill in the art at the time the invention was made to treat ulcerative colitis with a novel class of vitamin D related compounds inclusive of 20(S)-1.alpha.,25-dihydroxy-2-methylene-19-nor-vitamin D3. The motivation is because DeLuca et al teaches the vitamin D compounds exhibit pronounced activity in arresting the proliferation of undifferentiated cells and inducing their differentiation to the monocyte, and Wu teaches during inflammatory states such as ulcerative colitis and parasitic infections, there is an increase in epithelial proliferation with an expansion of cell populations in an undifferentiated state. Therefore, a skilled artisan would have reasonable expectation of successfully treating ulcerative colitis, with a vitamin D related compound, inclusive of 20(S)-1.alpha.,25-dihydroxy-2-methylene-19-nor-vitamin D3, which exhibits pronounced activity in arresting the proliferation of undifferentiated cells and inducing their differentiation to the monocyte.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,6,7, and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, and 8-11 of U.S. Patent No. 6,989,377. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the invention herein are drawn to a method of treating inflammatory bowel disease (ulcerative colitis) comprising administering to a patient an effective amount of a vitamin D compound with said formula, whereas the prior art is a method of treatment of ulcerative colitis comprising a vitamin D compound selected from 1, 25-dihydroxyvitamin D3 and a interleukin-10.

A skilled artisan would have reasonable expectation of successfully treating ulcerative colitis with a 1, 25-dihydroxyvitamin D3 compound.

Claims 1, 2, 4 and 7 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 56 of copending Application No. 11/283090. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the invention herein are drawn to a method of treating inflammatory bowel disease (ulcerative colitis) comprising administering to a patient an effective amount of a vitamin D compound with said

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formula, whereas the prior art is a method of treating an inflammatory disease such as an inflammatory bowel disease with a 1, 25-dihydroxyvitamin D3 compound.

A skilled artisan would have reasonable expectation of successfully treating an inflammatory bowel disease with a 1, 25-dihydroxyvitamin D3.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, and 4-7 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51, 52-55 of copending Application No. 11/283291. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the invention herein are drawn to a method of treating inflammatory bowel disease (ulcerative colitis) comprising administering to a patient an effective amount of a vitamin D compound with said formula, whereas the prior art is a method of treating an inflammatory disease such as an inflammatory bowel disease with a vitamin D3 compound.

It is obvious from the cited references that there is a desire in the prior art for application of vitamin D in patient treatment for auto immune disorders, inflammatory diseases, psoriasis, and the families of the diseases and disorders as discussed with each reference. The activity of the levels of vitamin D compounds are well documented with regards to the results desired in the prior art. A skilled artisan would have reasonable expectation of successfully treating an inflammatory bowel disease with a vitamin D3 compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, and 4-7 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51, 52-55 of copending Application No. 10/235244. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the invention herein are drawn to a method of treating inflammatory bowel disease (ulcerative colitis) comprising administering to a patient an effective amount of a vitamin D compound with said formula, whereas the prior art is a method of treating an autoimmune disease such as an inflammatory bowel disease with a vitamin D3 compound.

It is obvious from the cited references that there is a desire in the prior art for application of vitamin D in patient treatment for auto immune disorders, inflammatory diseases, psoriasis, and the families of the diseases and disorders as discussed with each reference. The activity of the levels of vitamin D compounds are well documented with regards to the results desired in the prior art. A skilled artisan would have reasonable expectation of successfully treating an inflammatory bowel disease with a vitamin D3 compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed March 18, 2008 have been fully considered. The response to the arguments is as discussed below:

Applicant argues Exhibit 1 teaches DP035 and DP066 both vitamin D3 analogs did not significantly reduce IBD in the treated animals. Applicant also states that differentiation although more potent than 1 α ,25-dihydroxyvitamin D3 in cell differentiation activity, the compound DP035 is ineffective in treating IBD and further that compound DP066 or VIT-III has "little difference" from 1 α ,25-dihydroxyvitamin D3 in its ability, i.e. both efficacy and potency, to promote HL-60 differentiation. In other words, DP066 or VIT-III is just as active in cell differentiation as 1 α ,25-dihydroxyvitamin D3. Hence, although just as active as 1 α ,25-dihydroxyvitamin D3 in cell differentiation, the enclosed data of Exhibit 1 show that DP066 or VIT-III is not effective against IBD. Therefore, Applicant argues it would not be obvious to treat inflammatory bowel disease such as ulcerative colitis with a vitamin D compound that exhibits pronounced cell differentiation activity.

In response, Examiner states that Exhibit 1 does not commensurate in scope with the claimed invention. More specifically, Applicant claims various analogs of vitamin D in treating all inflammatory bowel disease. The conclusion Applicant draws from Exhibit 1 and what is claimed by the Applicant is contradictory. Further, the large intestine weight and histopathological score data is not clearly presented in Exhibit 1. Applicant is asked to put Exhibit 1 in proper Declaration format.

Additionally, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention

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commensurate in scope with this claim. The instant claims are not enabled for methods of treating all inflammatory bowel diseases with various vitamin D analogs as claimed.

Applicant's argument over Obvious Double Patenting rejection of Application No. 10/235244, Application No. 11/283291, Application No. 11/283090, and U.S. Patent No. 6,989,377 depends on the validity of the previous arguments which were not found persuasive.

The arguments are not persuasive and the rejection is made **FINAL**.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-

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5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/
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